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Bonnie C. Harkness 24 Oct 1995  
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## INTRODUCTION

The main objective of this infrastructure project was to expand a population-based mammography registry to include every mammogram performed in practices in a 24 county area of North Carolina, which has a large rural, and black rural population. The goal is to link pathology data, mammography diagnostic data, outcome data and Quality data to study the patterns or use of mammography, and the patterns of practice of mammography in this distinct geographic region.

Previous to this application, a mammographic data retrieval system was developed by the investigators, and feasibility work performed to get it into practices outside of the academic medical center. The project was proposed for an area that was already organized for pathology retrieval for the Breast Cancer SPORE. Having the infrastructure in place would allow research on mammography outcomes, with the ability to compare women served by the CDC BCCCP program and to study differences between rural and urban, and black and white women.

## WORK IN PROGRESS

In the first year we have accomplished much according to our statement of work in the application.

### *Task 1: Organizational Development (0-6 months.)*

- a. Create oversight committee: to set policy, definitions and time tables, and promotional guidance for registry.*
- b. Create executive committee for practice recruitment: to design outreach program, and publicity for recruitment.*
- c. Create executive committee for pathologist recruitment: to establish approach for pathologist recruitment.*

We have created an advisory committee, which has met as a group one time, and been called for advice on individual basis. We have work groups that have guided us in our recruitment of practices and pathologists. We are presently working with the NCCCR and the NC Association of Tumor Registrars to create a mechanism for receiving all benign pathology data in addition to the cancer pathology data.

### *Task 2: Customize and install computer network and programs (0-12 months).*

- a. Design and install computer interface and linking programs to enable linkage to Lineberger CCC and NCCCR.*
- b. Establish confidentiality and quality control protocols*

Much has been accomplished in improving the applications software that is used in the practices for collection and tracking of mammography data.

The following tasks have been accomplished with the **Carolina Mammography DataSystem Software** since January 1, 1995:

- Original software code has been documented with directional, technical, and expletive statements for ease in maintenance and development tasks
- The primary mammogram database has been redesigned and divided into linked subsidiary databases to accommodate a growing variable data set recorded by the software
- Minor software enhancements have been made to the streamlined version of the software per the request of the pilot site
- Major software enhancements have been made to the general version to reflect data decisions rendered by the National Breast Cancer Surveillance Consortium. Additionally, screen designs have been altered to expedite data entry and promote site usability.
- New installation features have been added to the general distributed version that allows each site to customize the software to record relevant personnel and satellite location center information for reporting purposes
- The pathology user interface has been revamped and the ensuing changes made to the pathology database. An accompanying report feature has also been implemented to organize and display pathology data entered by the site in hardcopy format.
- A reporting module has been designed and instituted that helps facilities meet Federal Drug Administration/ Mammography Quality Standards Act. This module produces a monthly mammogram report outlining patients with positive mammograms, mammogram interpretation codes, and recommended follow-up procedures. It also generates a monthly summary report by individual radiologist which summarizes screening and diagnostic mammograms conducted on a monthly basis with summary data of the interpretation codes by the number of recommended follow-up tests ordered. Lastly, a referring physicians report can be generated for patients with positive mammogram results.
- A query system has been designed and coded that will track mammogram patients who have not returned for a recommended follow-up visit. This system provides the site with needed flexibility to categorize patients by type of recommended follow-up exam over any given time period within the database along with the display mode (i.e. Printed Report, Screen Display, or Text File saved to disk).

Over the past 12 months we have done extensive work to create, document, test and now are using a quality control system. All data received is run against the QC programs which check for inconsistent and missing data, and print reports which we send back to the practices for correction or clarification. The practices correct on the reports, and we edit the data at the research site. All data has identifying information stripped and unique ID's assigned. We are working on a plan to do spot double entry of data to test for error rates of data entry.



We have strict rules for guaranteeing confidentiality to the best of our ability. No reports sent to practices are kept on file in our research site, the only copy goes to the practice. We do not have any analysis files that are linked to pathology, or have identifying information. The original disks that are sent to us with downloaded data are kept in a locked cabinet.

We have been assured by the NC counsel for the public health department that a new state law that went into effect on 1 October 1995 protects the data from being accessed under the public freedom of information law. We lock our computers when not in use. In addition we are working within the National Breast Cancer Surveillance Consortium to apply for a US Public Health service certificate of confidentiality. We are pursuing every avenue open to us to guarantee confidentiality and protection of data, to the best of our ability.

*Task 3: Enroll Mammography practices and pathologists into registry (0-24 months)*

- a. *Contact every mammography practice in 24 counties to enroll in registry*
- b. *Demonstrate and install mammography database in interested practices*
- c. *Arrange for data transfer in practices already using a data system*
- d. *Arrange for paper data collection and transfer in practices choosing this option.e.*

*Establish process with each pathology site for acquisition of all breast pathology data: and expand process with those already cooperating with NCCCR, to acquire benign breast pathology*

We have been very successful in recruitment so far. We have enrolled 29 practice in 15 counties as of 10/25/95. All facilities in the 24 counties have been contacted. We will continue to bring the remaining practices into the registry steadily. The practices actively participating at the present time are listed below by county, and practice type.

| <b>Practice Type</b>                 |                 | <b>City</b> | <b>County</b> |
|--------------------------------------|-----------------|-------------|---------------|
| radiology unless otherwise specified |                 |             |               |
| 1)                                   | Hospital        | Burlington  | Alamance      |
| 2)                                   | Private         | Washington  | Beaufort      |
| 3)                                   | Hospital        | Pungo       | Beaufort      |
| 4)                                   | Hospital        | Windsor     | Bertie        |
| 5)                                   | Hospital        | Siler City  | Chatham       |
| 6)                                   | Private         | Durham      | Durham        |
| 7)                                   | Ob/Gyn Practice | Durham      | Durham        |
| 8)                                   | Medical Center  | Durham      | Durham        |
| 9)                                   | Hospital        | Smithfield  | Johnston      |
| 10)                                  | Private         | Smithfield  | Johnston      |
| 11)                                  | Hospital        | Williamston | Martin        |
| 12)                                  | Hospital        | Pinehurst   | Moore         |
| 13)                                  | Radiology       | Pinehurst   | Moore         |
| 14)                                  | Hospital        | Rocky Mount | Nash          |
| 15)                                  | Hospital        | Rocky Mount | Nash          |



|     |                   |              |            |
|-----|-------------------|--------------|------------|
| 16) | Family Practice   | Hillsborough | Orange     |
| 17) | Private           | Chapel Hill  | Orange     |
| 18) | Ob/Gyn Practice   | Chapel Hill  | Orange     |
| 19) | Academic Hospital | Chapel Hill  | Orange     |
| 20) | Ob Gyn practice   | Greenville   | Pitt       |
| 21) | Medical Practice  | Greenville   | Pitt       |
| 22) | Hospital          | Plymouth     | Washington |
| 23) | AFB Hospital      | Goldsboro    | Wayne      |
| 24) | Family Medicine   | Raleigh      | Wake       |
| 25) | Family Practice   | Raleigh      | Wake       |
| 26) | Private           | Raleigh      | Wake       |
| 27) | Hospital          | Cary         | Wake       |
| 28) | Private           | Raleigh      | Wake       |
| 29) | Hospital          | Wilson       | Wilson     |

In addition we have linked up with the North Carolina Breast Cancer Study (PI, Beth Newman, funding agency, NCI under the Breast Cancer SPORE), and the North Carolina Central Cancer Tumor Registry (NCCCR), and get weekly delivery of all fast reported breast cancers in the 24 counties.

The following materials have been developed in support of the data system being used by our participating practices.

- Data Management Guide
- Data collection manual--describes how to collect data on paper, definitions of interpretation codes, follow-up recommendations, etc.
- CMDS (Data system) User's guide
- Data Dictionary
- Documentation describing the QC reports for mammo facilities

*Task 4: Operate and Maintain Registry (0-36 months)*

- a. On-going data cleaning and entry*
- b. On-going quality control*
- c. Linkage to NC-CCR and Lineberger CCC*
- d. Respond to requests for shared use of registry data (beginning at 36 months)*

We are 'in business', actively bringing on new sites, running our QC reports, editing data, and feeding data back to the practices. We have pathology data arriving through the Lineberger Breast Cancer SPORE and the NCCCR, and are building a pathology database. We are optimistic that by this time next year, we will have data to report, as many practices will have been sending data for a year.

In addition to all this activity, the creation of this infrastructure enabled us to successfully compete to be funded by the National Cancer Institute to become part of the National Breast Cancer Consortium. This moves the project from being important to NC, and to the nation as a whole. The National Consortium is creating a core dataset that will allow pooling of data from 9 projects similar to CMR to be able to study screening mammography on a national scale, with the ability to compare different racial/ethnic groups, different locales and different urban/rural settings. It is a very exciting project, and we are thrilled to be a part of it. We have been very careful to avoid overlap of funding. The NCI monies allow us to begin research projects off this data, and guarantee the continuation of the registry beyond the 3 years of support under this DOD funded project. It is what one would hope for when building an infrastructure. We have plans to study the biology of screen-detected vs interval cancers in the diverse population we are studying, and have support to study follow-up of women with positive mammograms to treatment.